

HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Proposed New Rules: N.J.A.C. 8:43G-12A

Proposed Amendments: N.J.A.C. 8:43E-3.4 and 8:43G-36.3

Hospital Licensing Standards

Emergency Care for Sexual Assault Victims

Satellite Emergency Departments: Services in Satellite Emergency Departments

General Licensure Procedures and Standards Applicable To All Licensed Facilities

Enforcement Remedies: Civil Monetary Penalties

Authorized By: Heather Howard, Commissioner, Department of Health and Senior Services (with the approval of the Healthcare Administration Board, Michael J. Baker, Esq., Chair and in consultation with the Division on Women, Janice L. Kovach, Director and the Sexual Assault Nurse Examiner program).

Authority: N.J.S.A. 26:2H-1 et seq., particularly 26:2H-12.6b through g.

Calendar Reference: See Summary below for explanation of exception to the calendar requirement.

Proposal Number: PRN 2008-317.

Written comments on the proposal must be postmarked on or before December 5, 2008 and mailed to:

Ruth Charbonneau, Director
Office of Legal and Regulatory Affairs
Office of the Commissioner
Department of Health and Senior Services
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes new rules at N.J.A.C. 8:43G-12A and amendments at N.J.A.C. 8:43E-3.4 and 8:43G-36.3 in order to implement N.J.S.A. 26:2H-12.6b through g (P.L. 2005, c. 50), (hereinafter "the Act"). Former Governor Codey approved the Act on March 21, 2005.

N.J.A.C. 8:43G sets forth the rules and standards that apply to each licensed general or special hospital facility. The rules are intended to assure the high quality of care delivered in hospital facilities throughout New Jersey. The Act requires general hospitals and satellite emergency departments (hereinafter collectively referred to as "emergency health care facilities") to provide emergency care and medically and factually accurate and objective verbal and written information about emergency contraception and sexually transmitted diseases to all sexual assault victims. N.J.S.A. 26:2H-12.6c. In addition, the Act requires that emergency health care facilities verbally inform each sexual assault victim of her option to be provided emergency contraception at the facility and provide emergency contraception, upon her request, unless contraindicated. *Id.*

The Act requires emergency health care facilities to develop written policies and procedures that would ensure that all personnel who provide care or information to a sexual assault victim complete training on provision of medically and factually accurate and objective verbal and written information about emergency contraception and sexually transmitted diseases. N.J.S.A. 26:2H-12.6d. In accordance with the Act, the policies and procedures would also ensure that the personnel actually provide that information to a sexual assault victim. *Id.*

Pursuant to the Act, the Department formed a committee comprised of staff from the Division on Women, Office on the Prevention of Violence Against Women, New Jersey Coalition Against Sexual Assault and Sexual Assault Nurse Examiner program for developing and producing written information relating to emergency contraception and sexually transmitted diseases for distribution to emergency healthcare facilities. N.J.S.A. 26:2H-12.6e.

The Act requires the Commissioner to investigate complaints of noncompliance with the Act and this proposed subchapter, and prepare an annual report, available to the public, which summarizes substantiated complaints, and the actions taken by either the Commissioner or the emergency health care facility. N.J.S.A. 26:2H-12.6f. The Department has already set forth the process by which a person may file a complaint about any New Jersey licensed health care facility at N.J.A.C. 8:43G-1.4. In addition, N.J.A.C. 8:43G-4.1(a)28 requires all hospitals, which includes satellite emergency departments, to provide each patient with the contact information of the government agencies to which the patient can make a complaint and ask questions, including the Department's Complaint Hotline and to post this information conspicuously in public places throughout the hospital. Similarly, the Department has already established the requirement for confidential treatment of patient information at N.J.A.C. 8:43G-4.1(a)21.

Since the complaint and confidentiality requirements are set forth in the same chapter in which the Department proposes the new subchapter at N.J.A.C. 8:43G-12A, the Department does not repeat the complaint process in the proposed new subchapter. The Department does not anticipate that the annual report would be developed and published within approximately the next 24 months due to the length of time necessary to complete the administrative rulemaking process and implement N.J.A.C. 8:43G-12A. Therefore, the Department is not able to provide the method of public access to the annual report at this time. Interested persons may contact the Department's Office of Certificate of Need and Healthcare Facility Licensure at (609) 292-8773, with questions about the annual report.

The Act requires the Commissioner to promulgate rules, in consultation with the Division on Women and the Sexual Assault Nurse Examiner program to implement the purposes of the Act. N.J.S.A. 26:2H-12.6g. The Department's proposed new rules and amendments would fulfill this statutory mandate.

The Department proposes to amend N.J.A.C. 8:43E-3.4, governing civil monetary penalties, to add a penalty for an emergency health care facility's violation of any provision of proposed new N.J.A.C. 8:43G-12A or proposed N.J.A.C. 43G-36.3(b)4 (proposed amendment discussed below). The Department proposes to establish a penalty of \$ 5,000 per violation, which may be assessed for each day noncompliance is found.

The Department proposes to amend N.J.A.C. 8:43G-36.3, governing services required in satellite emergency departments for licensure. Specifically, the Department proposes an amendment at N.J.A.C. 8:43G-36.3(b)4 to require that satellite emergency departments provide each sexual assault victim emergency contraception, upon request, unless contraindicated and medically and factually accurate and objective verbal and written information about emergency contraception and sexually transmitted diseases consistent with N.J.A.C. 8:43G-12A, which would also apply to satellite emergency departments.

A summary of the proposed new rules at N.J.A.C. 8:43G-12A follows:

Proposed new N.J.A.C. 8:43G-12A.1 would articulate the purpose and scope of the new rules. The proposed new rules would apply to all emergency health care facilities, implement the Act, and promote the provision of emergency care to all sexual assault victims as established in the proposed subchapter.

Proposed new N.J.A.C. 8:43G-12A.2 would contain in one central location the documents that the Department incorporates by reference in this proposed subchapter. Specifically, the Department proposes to incorporate by reference the brochure entitled "For People Who Have Been Sexually Assaulted . . . What You Need To Know about STDs and Emergency Contraception," available in the subchapter Appendix, which is the brochure developed by the Department, in collaboration with the Division on Women, the New Jersey Coalition Against Sexual Assault and the Sexual Assault

Nurse Examiner program that provides information relating to emergency contraception for the prevention of pregnancy in sexual assault victims and sexually transmitted diseases. Proposed new N.J.A.C. 8:43G-12A.2 would also set forth the methods by which the brochure is available.

Proposed new N.J.A.C. 8:43G-12A.3 would provide definitions of the words and terms used in this proposed subchapter. Proposed new N.J.A.C. 8:43G-12A.3(a) would articulate that the following terms shall have the same definitions as established in the Act at N.J.S.A. 26:2H-12.6b: "Division on Women," "emergency care to sexual assault victims," "emergency contraception," "medically and factually accurate and objective," "sexual assault nurse examiner program," "sexual assault victim" and "sexual offense." Proposed new N.J.A.C. 8:43G-12A.3(b) would establish definitions of the following terms: "Act," "Commissioner," "Department" and "'emergency health care facility' or 'facility.'"

Proposed new N.J.A.C. 8:43G-12A.4 would set forth the requirement for the provision of emergency care to sexual assault victims by emergency health care facilities. Proposed new N.J.A.C. 8:43G-12A.4(a) would establish the standard of care for sexual assault victims who present at emergency health care facilities and would require the facilities to provide medically and factually accurate and objective verbal and written information on emergency contraception and sexually transmitted diseases and provide emergency contraception upon request, unless medically contraindicated. Proposed new N.J.A.C. 8:43G-12A.4(b) would establish that the Department does not require emergency health care facilities to provide emergency contraception to a sexual assault victim who is pregnant.

Proposed new N.J.A.C. 8:43G-12A.5 would set forth the requirement that emergency health care facilities develop policies and procedures for training personnel who treat victims of sexual assault and to ensure provision of the care established at proposed N.J.A.C. 8:43G-12A.4(a).

Proposed new N.J.A.C. 8:43G-12A.6 would require emergency health care facilities to provide each sexual assault victim a copy of the brochure entitled "For People Who Have Been Sexually Assaulted . . . What You Need To Know about STDs and Emergency Contraception." The Department developed the brochure in collaboration with the Division on Women, the New Jersey Coalition Against Sexual Assault, and the Sexual Assault Nurse Examiner program and it contains information relating to emergency contraception for the prevention of pregnancy in sexual assault victims and sexually transmitted diseases.

Proposed new N.J.A.C. 8:43G-12A.7 would articulate the Department's authority to investigate every complaint of noncompliance with the Act or this subchapter in accordance with N.J.S.A. 26:2H-12.6f(a).

Proposed new N.J.A.C. 8:43G-12A.8 would establish the penalty for violation of the Act or the proposed subchapter.

Because the Department has provided a 60-day comment period for this rulemaking, this rulemaking is exempt from the calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Department believes that the proposed new rules and amendments would have a positive social impact on emergency health care facilities, consisting of approximately 77 general hospitals and five satellite emergency departments, and sexual assault victims that seek emergency care at the facilities. The State Police Uniform Crime Report for 2006 indicates 1,200 victims of rape in that year. This figure is about average over the past five years. The victimization of a woman through sexual assault is compounded, not only by the possibility of contracting a sexually transmitted disease, but also by the possibility that the sexual assault victim may suffer an unwanted pregnancy. Emergency health care facilities can take basic steps to help alleviate some of the trauma associated with sexual assault by providing sexual assault victims with immediate information about sexually transmitted diseases and emergency contraception and access to emergency contraception.

Medical research strongly indicates that a sexual assault victim has a better chance of preventing unintended pregnancy the sooner emergency contraception is administered following a sexual assault. The United States Food and Drug Administration (FDA) has approved the use of emergency contraception as safe and effective in the prevention of pregnancy. (United States Food and Drug Administration, "Prescription Drug Products: Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception," 62 FR 37, 8610 (Feb. 25, 1997)). Estimates show that increased use of emergency contraception could reduce the number of unintended pregnancies that occur each year by half.

The provision of emergency contraception is considered to be the accepted standard of care for treatment of sexual assault victims by the American College of Obstetricians and Gynecologists, the American Medical Association and the American College of Emergency Physicians. Ten states (California, Massachusetts, Minnesota, New Mexico, New York, Ohio, Oregon, South Carolina, Washington and Wisconsin) have enacted explicit emergency room emergency contraception laws that ensure that sexual assault victims receive access to emergency contraception in hospitals. Fourteen states (Arkansas, California, Colorado, Illinois, Massachusetts, Minnesota, New Mexico, New York, Ohio, Oregon, Pennsylvania, Texas, Washington and Wisconsin) currently require emergency rooms to provide information about emergency contraception to sexual assault victims.

Proposed new N.J.A.C. 8:43G-12A.2 would provide guidance to the regulated community in establishing definitions of words and terms used in the Act and in the proposed subchapter. The social impact of these definitions would be reflected as they are applied in the Act and in the subchapter. Proposed new N.J.A.C. 8:43G-12A.4 and

12A.5 would have a beneficial social impact on both the regulated community and sexual assault victims by articulating the standard of care for and requiring policies and procedures on the provision of emergency care to sexual assault victims, allowing for consistent treatment of victims that seek treatment in emergency care facilities. The proposed amendment at N.J.A.C. 8:43G-36.3 would provide consistency in an existing subchapter regarding the standard of care for sexual assault victims that seek treatment at satellite emergency departments. Proposed new N.J.A.C. 8:43G-12A.6 would have a beneficial social impact by providing a standard document that contains information relating to sexually transmitted diseases and emergency contraception, thereby empowering sexual assault victims with necessary medical information to ask questions and make health care decisions. Proposed new N.J.A.C. 8:43G-12A.7 would have a beneficial social impact in that it would highlight the obligation of emergency health care facilities to either enforce the Act and proposed new N.J.A.C. 8:43G-12A, or be subject to a complaint and investigation. As discussed in the Summary above, the Department has already set forth in existing rules the process for filing a complaint about any health care facility, which as relevant to the proposed new subchapter, has the beneficial social impact of providing a mechanism for sexual assault victims to report situations where they may not have received appropriate emergency care. Similarly, as discussed in the Summary above, the Department has already established in existing rules the requirement for confidential treatment of patient information, which has the beneficial social impact of protecting the personal medical information of sexual assault victims. Proposed new N.J.A.C. 8:43G-12A.8 and the proposed amendment at N.J.A.C. 8:43E-3.4 would have a beneficial social impact by reminding interested persons of the fines for violations the Act or the proposed subchapter and setting forth the applicable fines.

Economic Impact

The proposed new rules and amendments would have an economic impact on the approximately 77 general hospitals and five satellite emergency departments throughout New Jersey. Depending on the level of services currently offered, emergency health care facilities may incur some nominal costs in complying with the requirements of the proposed new rules and amendments. Specifically, emergency health care facilities may incur costs in order to fulfill the requirement that staff be trained and knowledgeable about the provision of emergency care to sexual assault victims. Additionally, emergency health care facilities may incur costs associated with making available and providing emergency contraception. Emergency health care facilities may incur costs for copying or printing the required brochure in sufficient amounts for those facilities but the facilities would realize some cost savings since the Department has compiled the information into one brochure and provides the brochure in English and Spanish.

The proposed amendment at N.J.A.C. 8:43E-4.3 would provide civil monetary penalties for facilities that fail to comply with N.J.A.C. 8:43G-12A and 36.3(b)4, governing emergency care for sexual assault victims. The Department anticipates that the proposed amendment to N.J.A.C. 8:43E-4.3 would have a negative economic impact on emergency health care facilities that violate the applicable requirements. The

Department anticipates, however, that the proposed civil monetary penalties will have a positive impact on compliance with the Act, proposed N.J.A.C. 8:43G-12A and 36.3(b)4 by emergency health care facilities. The Department expects that facilities will satisfy the requirements to avoid the commission of violations and the resulting penalty assessment. If this impact were realized, the overall negative impact would be reduced. In addition, proposed N.J.A.C. 8:43G-12A.8 would provide that any penalties imposed for noncompliance would be allocated, on a quarterly basis, to designated rape crisis centers. Therefore, assessed penalties would have a positive economic impact on the designated rape crisis centers.

Federal Standards Statement

The Department proposes new rules and amendments under the authority of N.J.S.A. 26:2H-1 et seq., particularly 26:2H-12.6b through g, not under the authority of or in order to implement, comply with or participate in any program established under Federal law or standards or under a State statute that incorporates or refers to Federal law, standards or requirements. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department believes that the proposed new rules and amendments would not have an adverse impact on jobs. Conversely, the proposed new rules and amendments may generate employment opportunities at emergency health care facilities as they may increase staff in areas of training, clinical expertise, and quality improvement to comply with the requirements to provide enhanced services to victims of sexual assault.

Agriculture Industry Impact

The proposed new rules and amendments would not have any impact on the agriculture industry.

Regulatory Flexibility Statement

The proposed new rules and amendments would impose recordkeeping and compliance requirements only on licensed general hospitals, which include satellite emergency departments, none of which is a "small business" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as each employs more than 100 people full-time. Therefore, a regulatory flexibility analysis is not required.

Smart Growth Impact

The proposed new rules and amendments would not have an impact on the achievement of smart growth or the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The proposed new rules and amendments would not have an impact on the costs associated with housing because the proposed rules only apply to emergency health care facilities in New Jersey with regard to their provision of emergency care for sexual assault victims.

Smart Growth Development Impact

The proposed new rules and amendments would not have an impact on housing production because the proposed new rules and amendments do not apply to housing. The proposed new rules and amendments apply to emergency health care facilities' provision of emergency care for sexual assault victims, which does not pertain to the production of housing.

Full text of the proposed new rules and amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

CHAPTER 43E
GENERAL LICENSURE PROCEDURES AND STANDARDS
APPLICABLE TO ALL LICENSED FACILITIES

SUBCHAPTER 3. ENFORCEMENT REMEDIES

8:43E-3.4 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2H-13 and 14, the Commissioner may assess a penalty for violation of licensure rules in accordance with the following standards:

1.-13. (No change.)

14. For failure of an entity licensed in accordance with N.J.S.A. 26:2H-1 et seq. to submit a serious preventable adverse event report to the Department in a timely fashion, as defined in N.J.A.C. 8:43E-10.6, the following, which shall be levied from the date following the date the report was due to be submitted to the Department until the date on which the report is received by the Department:

i. (No change.)

ii. \$ 250.00 per day for all other facilities, with the maximum penalty assessed per event not to exceed \$ 25,000; [and]

15. For failure of an entity licensed in accordance with N.J.S.A. 26:2H-1 et seq. to disclose to a patient or resident, pursuant to N.J.A.C. 8:43E-10.7, a serious preventable adverse event that affected that patient or resident, the following:

i. (No change.)

ii. \$ 5,000 for failure to disclose an event that the health care facility reported, in a timely manner, to the Department[.]; **and**

16. For violation of N.J.A.C. 8:43G-12A or 36.3(b)4, governing emergency care for sexual assault victims, \$ 5,000 per violation, which may be assessed for each day noncompliance is found.

(b)-(c) (No change.)

CHAPTER 43G
HOSPITAL LICENSING STANDARDS

SUBCHAPTER 12A. EMERGENCY CARE FOR SEXUAL ASSAULT VICTIMS

8:43G-12A.1 Purpose and scope

(a) The purpose of this subchapter is to:

1. Implement N.J.S.A. 26:2H-12.6b through g (P.L. 2005, c. 50);

2. Promote the provision of emergency care to sexual assault victims by all emergency health care facilities; and

3. Establish the standard of care for all emergency health care facilities to provide sexual assault victims with:

i. Verbal and written information about emergency contraception and sexually transmitted diseases; and

ii. Emergency contraception, upon their request.

(b) This subchapter applies to all emergency health care facilities.

(c) This subchapter covers emergency care to sexual assault victims, training of personnel at emergency health care facilities, availability of written emergency contraception and sexually transmitted disease information, compliance and penalties.

8:43G-12A.2 Incorporated documents

(a) The Department incorporates by references in this subchapter the brochure entitled, "For People Who Have Been Sexually Assaulted . . . What You Need To Know about STDs and Emergency Contraception," which is the brochure

developed by the Department, in collaboration with the Division on Women, the New Jersey Coalition Against Sexual Assault and the Sexual Assault Nurse Examiner program that provides information relating to emergency contraception for the prevention of pregnancy in sexual assault victims and sexually transmitted diseases and is available:

1. In the subchapter Appendix; and

2. In PDF format, in English and Spanish, at the Department's webpage, <http://nj.gov/health/cd/std/edu.shtml>.

8:43G-12A.3 Definitions

(a) The following words and terms, when used in this subchapter, shall have the meanings established at N.J.S.A. 26:2H-12.6b.

"Division on Women"

"Emergency care to sexual assault victims"

"Emergency contraception"

"Medically and factually accurate and objective"

"Sexual assault nurse examiner program"

"Sexual assault victim"

"Sexual offense"

(b) The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Act" means N.J.S.A. 26:2H-12.6b through g (P.L. 2005, c. 50) and this subchapter.

"Commissioner" means the Commissioner of the Department of Health and Senior Services or his or her designee.

"Department" means the Department of Health and Senior Services.

"Emergency health care facility" or "facility" means a general hospital or satellite emergency department licensed pursuant to N.J.S.A. 26:2H-1 et seq. (P.L. 1971, c. 136) and the Department's Hospital Licensing Standards at N.J.A.C. 8:43G.

8:43G-12A.4 Emergency care for sexual assault victims

(a) Each emergency health care facility shall provide emergency care to a sexual assault victim, including:

1. Medically and factually accurate and objective verbal and written information about emergency contraception and sexually transmitted diseases, as set forth at N.J.A.C. 8:43G-12A.6;

2. Verbal information regarding the option to receive emergency contraception at the facility; and

3. Emergency contraception upon request, unless contraindicated.

i. The emergency health care facility's provision of emergency contraception shall include the initial dose that the victim may take at the facility, the follow-up doses that the victim can self-administer later and applicable instructions.

(b) The Department does not require an emergency health care facility to provide emergency contraception to a sexual assault victim who is pregnant.

8:43G-12A.5 Policies and procedures concerning personnel training

(a) Each emergency health care facility shall establish written policies and procedures to ensure that all personnel who provide care or information to a sexual assault victim:

1. Complete mandatory training to provide medically and factually accurate and objective verbal and written information about emergency contraception and sexually transmitted diseases to a sexual assault victim;

2. Provide the care and information set forth at N.J.A.C. 8:43G-12A.4(a) for each sexual assault victim; and

3. Document in writing the provision of care and information to each sexual assault victim.

8:43G-12A.6 Written information on emergency contraception and sexually transmitted diseases for sexual assault victims

(a) Each emergency health care facility shall provide each sexual assault victim a copy of the brochure entitled "For People Who Have Been Sexually Assaulted . . . What You Need To Know about STDs and Emergency Contraception."

(b) The Department shall make a copy of the brochure entitled, "For People Who Have Been Sexually Assaulted . . . What You Need To Know about STDs and Emergency Contraception," available to each emergency health care facility through the methods set forth at N.J.A.C. 8:43G-12A.2.

8:43G-12A.7 Investigation and compliance

The Department shall investigate every complaint of an emergency health care facility's noncompliance with the provisions of the Act, in accordance with N.J.S.A. 26:2H-12.6f(a), including the failure of a facility to provide the services required by the Act.

8:38G-12A.8 Penalties

(a) If the Department determines that an emergency health care facility has violated any provision of the Act, the Department may assess the penalty established at N.J.A.C. 8:43E-3.4(a)16.

1. All penalties assessed pursuant to (a) above shall be allocated on a quarterly basis to the Division on Women for supplemental funding for designated rape crisis centers.

APPENDIX

Emergency Contraceptive Pamphlets [[English](#) pdf 452kb – [Español](#) pdf 432kb]

8:43G-36.3 Services in satellite emergency departments

(a) (No change.)

(b) All satellite emergency departments applying for licensure shall provide the following services:

1. (No change.)

2. Basic and stat laboratory services including:

i.-vii. (No change.)

viii. Pregnancy tests; [and]

3. Basic radiology services, which shall include at a minimum non-enhanced and non-contrast radiographs[.]; and

4. Emergency contraception, upon request, to sexual assault victims and medically and factually accurate and objective verbal and written information

about emergency contraception and sexually transmitted diseases, pursuant to N.J.A.C. 8:43G-12A.

(c)-(d) (No change.)